



**New Jersey Department of Health and Senior Services
Governor's Council for Medical Research and Treatment of Autism
Meeting Minutes – June 20, 2011 (ratified)
6pm – 9pm**

**Location: NJ Department of Health and Senior Services, Health & Agriculture Building,
369 South Warren Street, Trenton, NJ 08625-0360**

Council Members Present

Elizabeth K. Bell, BS, volunteer and independent contractor with Autism Speaks,
Autism Organization Representative

Caroline Eggerding, MD, Vice President Clinical Services, Bancroft NeuroHealth,
Healthcare Organization Representative and Chair of Governor's Council for Medical Research
and Treatment of Autism

Susan P. Evans, EdD, Education Program Specialist for Early Intervention Program,
Commissioner of Health and Senior Services Appointee

B. Madeleine Goldfarb, MA, Founder/Director of the Noah's Ark Children's Association,
Autism Organization Representative

Ketan Kansagra, MD, FAAP, Children's Hospital of New Jersey at Newark Beth Israel Medical
Center, Academic Institution Recommendation

Linda S. Meyer, EdD, MPA, BCBA-D Executive Director of Autism New Jersey, Autism
Organization Representative

Kendell R. Sprott, MD, JD, Acting Director of Pediatrics, University of Medicine and Dentistry-
New Jersey Medical School, Academic Institution Representative

Absent

Grace M. Reilly, RN, MSN, APN-C, Adult Nurse Practitioner for Riverview Medical Center,
Individual with Autism or Family Member Representative

Judah Zeigler, Associate Vice President of Sharp's Retail and Consumer Marketing, Senate
President Appointee

Barbie Zimmerman-Bier, MD, Appointment at Rutgers University, clinician at St. Peter's University, Academic Institution Representative

NJ Department of Health and Senior Services (DHSS) Attendees

Martin T. Zanna MD, MPH
Acting Executive Director
Governor's Council for Medical Research and Treatment of Autism

Cynthia Kirchner, MPH
Director, Quality Improvement
Ethics Liaison for the DHSS

Linda N. Bocclair, M.Ed., MBA
Executive Assistant
Governor's Council for Medical Research and Treatment of Autism

Mary Ray, Contract Administrator 2
Governor's Council for Medical Research and Treatment of Autism
Commission on Brain Injury Research
Commission on Spinal Cord Research

General Public Attendees

Audrey Mars, MD
Medical Director, Regional Autism Center at Hunterdon Medical Center

Pnina Mintz, Ph.D.
Center for Neurological and Neurodevelopmental Health (CNNH)

Denise Aloisio, MD
Medical Director
Jersey Shore University Medical center

Carole Deitchman
Caldwell College

Eric Synder
Office of Intergovernmental Affairs
Office of the Governor

Jill Harris, Ph.D.
Children's Specialized Hospital

Walter Zahorodny, Ph.D.
UMDNJ New Jersey Medical School

Kelly Carlile
Caldwell College

Natalia Szmackinski
Caldwell College

Michelle Smith
Caldwell College

Madeleine Kautz
Caldwell College

Tara Gleeson
Morrisville Hospital

I. Welcome - Council Chair, Dr. Caroline Eggerding called the meeting to order at 6:15PM and welcomed everyone.

II. Public Meetings Act Announcement- Dr. Eggerding read the Public Meetings Act Announcement, followed by roll call.

III. Department of Health and Senior Services Update

To keep the Council informed of the activities in the Department of Health and Senior Services (DHSS), Ms. Cynthia Kirchner provided an update on the changes in the Department. In December, the Council was moved from the Division of Family Health Services (FHS) to the Office of Policy and Strategic Planning in the Office of the Commissioner. The autism staff continues to work closely with FHS and FHS is represented on the Council.

Ms. Cathleen Bennett is the Director of the Office of Policy and Strategic Planning and Ms. Kirchner is the Director of Quality Improvement and oversees the Council, on behalf of Commissioner O'Dowd, and both the Commission on Spinal Cord Injury and the Commission on Brain Injury. Ms. Kirchner appreciates the opportunity to work with the Council and thanked the members for their contributions and commitment to serving on the Council.

In March, Commissioner Poonam Alaigh resigned from her position as Commissioner due to family obligations and Ms. Mary O'Dowd was appointed Acting Commissioner and sworn in as Commissioner on June 3, 2011. Prior to her appointment Ms. O'Dowd served as Acting Deputy Commissioner of Senior Services and Health Systems for DHSS. Ms. O'Dowd is currently on maternity leave with Dr. Tina Tan, Acting Deputy Commissioner, serving as Acting Commissioner. While there have been several changes in the Department over the past six months, Ms. Kirchner noted that the Department is moving in the right direction.

IV. Code of Ethics

Ms. Kirchner referred to the Autism Council's Code of Ethics that was approved on May 24, 2011 by the State's Ethics Commission. She asked that the Council review and take seriously the document. The Code of Ethics is intended to establish standards of conduct while protecting the Council and the State from accusations of conflict of interest. The Council's Code of Ethics is a short document based on the Codes of Ethics for the Commission on Brain Injury and the Commission on Spinal Cord Injury and addresses several of the provisions of the New Jersey Conflicts of Interest Law and the Uniform Ethics Code. Of the fourteen issues addressed in the Code of Ethics, Ms. Kirchner highlighted four that are particularly relevant to the Council:

#7: An Autism Council Member cannot write a letter of support for a grant application for funding by the Autism Council.

#8: An Autism Council Member cannot sign a grant application on behalf of his/her institution/employer when the institution/employer is applying to the Autism Council for funding.

Council members are Special State Officers assisting the State, the DHSS and the Governor in moving forward the research agenda and conditions for research as outlined in the Statute, P.L. 2007, c.168. It is very important that members are not compromised in anyway with the information that they are provided while sitting on Council. Compliance with the Code of Ethics will ensure that members cannot be accused of being privy to information that gives them an added advantage to provide information to their employer, to academic institutions or to any group or individual planning to or applying for Council funded grants. As we move forward Council members will be voting on funding research grants. There needs to be a clear distinction between one's role as a Council member and that of a potential grant recipient.

#9: Autism Council Members are not permitted to be primary investigators, co-investigator, sub-grantees or collaborators on grant applications submitted to the Autism Council.

While what happened in the past cannot be changed, moving forward, under the Code of Ethics, Council members will be afforded the appropriate protection from accusations of conflicts of interest.

#11: An Autism Council Member whose institution/employer applies for an Autism Council grant is barred from any official involvement with that grant application.

Ms. Kirchner and the Council staff reviewed the current grants to ensure that anyone who had a potential conflict of interest recused themselves. The recusal letters are on file in the Autism office.

Members can sit on Council if they are completely removed from every capacity of a grant application submitted by the institution where they work or by the institution they are representing and recuse themselves from the vote for the institution where they are employed. Any Council member who has a potential conflict or is interested in applying for Council

funding should talk with Ms. Kirchner, Dr. Zanna or Dr. Eggerding to ensure that the member is cleared of any potential conflict of interest.

Ms. Kirchner noted that any Council member who has not completed the ethic training and/or signed the Conflict of Interest form and submitted documentation to the Council staff cannot vote at tonight's meeting. Members must comply with all requirements to be considered in good standing. Only members in good standing are permitted to participate in the Council meetings. Members are required to complete an annual ethics training update requiring 30-40 minutes. Ms. Kirchner thanked the Council for their cooperation.

V. Approval of the February 28, 2011 Council Meeting Minutes

Dr. Eggerding called for a motion to approve the minutes. MOTION by Dr. Sprott to approve the minutes was seconded by Ms. Bell. No discussion.

MOTION to approve the minutes as presented was passed with all in favor.

VI. Election of the Chairperson

Dr. Eggerding noted that the Statute requires a Chairperson to be elected at the first meeting of each calendar year. The election was delayed this year to allow time for all ethics questions to be answered before moving forward. Council was given the choice to either elect a Chairperson or to delay until the September meeting when three new members will join the Council. After a brief discussion, a motion by Dr. Sprott to elect a chairperson and not delay was seconded by Dr. Evans.

MOTION to elect a Chairperson and not delay was passed with all in favor.

Dr. Eggerding noted that the floor was opened for nominations. Dr. Sprott nominated Dr. Eggerding. With no additional nominations, the floor was closed for nominations, voting ballots were distributed and tallied and Dr. Eggerding was elected Chairperson by a majority vote. Dr. Eggerding thanked everyone for their support.

VII. Report of the Acting Executive Director

Administration

Dr. Zanna reported that he attended several educational symposiums: (1) "Understanding Autism From the Inside Out" at St. Peter's University Hospital in New Brunswick on April 27 where the guest speaker, Dr. Craig Newschaffer, was very enlightening and spoke of current trends in epidemiology research in helping to search for environmental autism risk factors; (2) "Autism Spectrum Disorders: Understanding an Urgent Public Health Concern" conference co-sponsored by NJDHSS and CDC Conference on April 29 at Children's Specialized Hospital in New Brunswick where a tabletop display highlighting the work of the Council was presented. The conference was well received with New Jersey First Lady Mary Pat Christie and Commissioners O'Dowd and Velez in attendance. Dr. Audrey Mars, Hunterdon Medical Center, who is with us tonight, received a CDC recognition award largely for her work in assisting CDC in research to

track the prevalence of ASD; (3) “The Dollars and Sense of Prevention” on June 8 in Hamilton, sponsored by the Governor’s Council on the Prevention of Developmental Disabilities and followed by a retirement dinner for Dr. Deborah Cohen. Dr. Cohen is the Director of the Office on Autism, Department of Human Services and the Executive Director of Council on the Prevention of Disabilities. Commissioner Velez and former Commissioner Smith were in attendance. The Department of Health and Senior Services (DHSS) has appointed Dr. Zanna to The Interagency Task Force for Autism representing the DHSS and the Council. In addition to the conferences listed above, Ms. Bocclair attended Children’s Specialized Hospital’s Autism symposium held on March 18 at the Pines Manor in Edison. The symposium was well received with over 250 parents and professionals in attendance. Nationally recognized speakers presented on topics in the morning ranging from research studies and clinical services to autism from the perspective of a parent. A series of presentations and open discussions for parents and caregivers of children and young adults with ASD was held throughout the afternoon. The presentations were very informative as was the sharing of successes and challenges among the participants.

Website

In response to Council’s request, all of Council’s meeting minutes from December 2008 to December 2010 are now posted on the Council website on the “Reports/News/Meeting Minutes” page. Meeting minutes, including the February 28, 2011 minutes, will be posted as they are approved by Council. Mid-year reports from the Clinical Enhancement Centers and from the 2010-2012 Research Grantees are posted on the “Current Grants Initiative” page. The Code of Ethics has been submitted for posting.

Grant Monitoring

Site visits and quarterly reports

Dr. Zanna noted that he, along with Dr. Danuta Buzdygan (Pediatric Consultant) and Linda Bocclair conducted four site visits at the Clinical Enhancement Centers since the February 28 Council meeting. The first was the University of Medicine and Dentistry’s in Newark on March 22 followed by the Center for Neurological and Neurodevelopmental Health (CNNH) in Gibbsboro on March 28, Jersey Shore University Medical Center in Neptune on May 13 and; Children’s Specialized Hospital in Toms River on June 14. Hackensack University Medical Center is scheduled for June 30. Quarterly Reports were reviewed in preparation for the site visits. Dr. Lori Garg and Ms. Bocclair visited Hunterdon Medical Center and Ms. Bocclair reported at the December Council meeting that they were impressed with the expertise and commitment of the staff and that Hunterdon met and often exceeded their grant requirements.

Dr. Zanna indicated that he is drafting the site visit reports with the team and offered his initial impressions. Each of the four Centers visited provide excellent services. While their goals and objectives differ, as does the diversity of models, commonalities among the Centers serve as a foundation on which to compare and evaluate the various elements of their programs. All of the Centers have highly qualified Principal Investigators and key staff. While there are variations in their approaches, the use of state of the art diagnostics and therapies is impressive. Briefly, examples include Digital Sense Array Electroencephalography (EEG), Autism Diagnostic Observation Schedule (ADOS) in virtually all Centers and genetics testing generally available

with one Center having a geneticist as a team member. All Centers emphasized the importance of multidisciplinary teams and most of the Centers reach out beyond their respective counties to provide services. Several of the Principal Investigators are active at the national level and at least three Centers are involved in clinical trials for pharmacological research. Two of the Centers (Children's Specialized Hospital and CNNH) will present to Council at the September 12, 2011 meeting and the remaining four Centers will present later in the year.

Council questioned the significant variability of numbers of children served, as reported by the Centers in their mid-year reports and questioned if there was a process in place to monitor efficiencies. Dr. Zanna noted that the site visit team looked at trends in numbers and, in general, in what each Center said they would do as compared to what they accomplished. There has been an upward trend, in the aggregate, in the total number of patient visits between 2009 and 2010. The goals among the Centers differ significantly based on what each sees as enhancements for their respective Center.

Additional issues that need to be addressed as the Council moves forward with funding for the new RFAs include the use of the Collaborative Database, standardizing procedures, wait times for appointments and follow-up, early diagnosis, how wait times are defined by each Center and the impact of a parent registering at multiple Centers. There needs to be consideration for ensuring economies of scale and including Centers with the numbers of patients that would provide a critical mass for meaningful research outcomes, as well as cost effectiveness.

Collaborative database

A total of 241 patients have been added to the Collaborative database with significant variation among the Centers due, in part, to the delays in Centers receiving IRB approvals. In moving forward with the RFAs, measures and data points that need to be collected will be added and the RFAs will clearly define the requirements for data collection and reporting, including IRB approvals. The Collaborative Database was set up as a research database for the six Clinical Enhancement Centers and requires consent by patients/caregivers for participation.

Conference call

A Conference call was held on March 24, 2011 with the Clinical Enhancement Center PIs and several Center staff. In addition to the Council staff, Drs. Nancy Scotto Rosato and Sandy Howell participated in the call as did Drs. Meyer and Zimmerman-Bier and Ms. Goldfarb. Topics included a discussion of the procedure for requesting a no cost extension, collaborative database update by the Centers and issues/questions re: expenditure reports and the SAGE system. Most of the questions by the PIs and staff were related to the Collaborative Database and answered by Drs. Scotto-Rosato and Howell. Dr. Meyer asked if all Centers had submitted reports. The mid-year summary reports were due March 17, 2011. Two Centers were late in submitting reports but were expected to submit by March 28, 2011.

Autism NJ Conference

Grantees were notified of the opportunity to present their research at a poster session event on October 13, 2011 at Autism New Jersey's 29th Annual Conference in Atlantic City. Applications

are due by August 12, 2011. Linda Meyer, Executive Director of Autism NJ, commented that one researcher applied and she noted that presenting at the poster session is a wonderful opportunity for researchers to meet hundreds of people with their posters located in a highly visible location on the 4th floor of the conference. She also noted that this is the first time for Council funded researchers to present at the poster session and there is no charge to the Council.

NJ Autism Center of Excellence (NJACE) RFAs

The RFAs are being reviewed internally with a consultant in order to streamline the production of a comprehensive RFA, given that there are many pieces that must be aligned to ensure a functional system. With respect to the database component, the Department is working closely with the Office of Information and Technology Services and Family Health Services on the optimal database elements and integration with the Collaborative Database. To ensure that the State will be in a position to apply for federal funding, the Collaborative database must be aligned with the national autism research database (NDAR). Release of the RFAs is anticipated this fall.

VIII. Rutgers University MOA Needs Assessment

The Interim Report will be submitted by Rutgers the first week in July, 2011. A copy will be sent to Council for review and Dr. Dorothy Gaboda will attend the September 12, 2011 Council meeting to discuss the report. In response to the question of input from the Council, while the initial plan was to interview Council members it was later decided that a more efficient use of time would result from distributing a survey to Council since Rutgers charge was to provide feedback from external sources not to report on what was already known by Council.

IX. Recommendation from Dr. S. Evans re: Proposed addition of “Responsibilities of Council Members” to the Rules of Order

Several meetings ago the Council was considering an expansion of the Council’s Rules of Order. After discussion the plan was to solicit additional input from Council and ask Dr. Evans to review and make a recommendation at a later meeting of the Council.

Dr. Eggerding referred to Dr. Evans for her recommendation. The MOTION, made by Dr. Evans to leave the Rules of Order as they stand without modifications, was seconded by Dr. Meyer. Dr. Evans commented that only one person provided feedback and that the Code of Ethics, recently approved by the State Ethics Commission, helped to clarify issues. The question was asked if the issue of attendance is in the Rules of Order. It was added last summer—if a member misses greater than 50% of the meeting in one year the Council can recommend removal of the member. The new rule must be in effect for a full year before it can be enforced. Regular attendance records are filed in the Autism Council office. The Governor’s Office is interested in feedback regarding attendance since fewer members result in a smaller knowledge base making it more difficult to engage in meaningful discussions and outcomes.

MOTION to leave the Rules of Order as they stand without modifications was passed with all in favor.

X. Scientific Advisory Committee (SAC)

Establishing the five-member SAC is a requirement of the Statute and is the responsibility of the Executive Director. A list of potential out-of-state members previously developed and distributed to Council will be sent to Council to update and recommend their top choices. While potential members may have been previously invited and declined it was noted that timing may have been a factor with conflicting priorities and should not preclude the Executive Director from contacting potential members. Dr. Zanna noted that he had outreached to Dr. Kau at NIH for her recommendations, including Principal Investigators from the federal Autism Center of Excellence (ACE) projects.

XI. Report of the Basic Science Grants (2000-Present) Sub-committee

Ms. Goldfarb reported, with a great deal of enthusiasm, on the new Council initiative, the start of what we hope to ultimately be a statewide program to bring all autism researchers together annually for a summit to present and hear about the “State of the State of Autism Research in New Jersey”.

Research Grantees were notified on June 10, 2011 that the Governor’s Council is planning to host a scientific meeting in March 2012 and encouraged grantees to join their colleagues to share their research – successes and challenges. Ms. Goldfarb noted that by convening all basic and clinical science grantees to report on their finding, there are opportunities for collaborations and for the Council to report to stakeholders on how Council funded research has moved the knowledge base forward in the State.

Of the 28 researchers contacted (including all from 2000 to present), 9 emails were returned undelivered and 9 expressed interest in participating in the meeting. Ms. Bocclair will follow-up on those returned undelivered and send a second email to those who do not respond by June 30, 2011.

It was noted that moving forward all grantees should be obligated to present their research findings. The amount of funding for each grant is significant as compared to the small grants awarded during the earlier years of funding research. Council is also interested in how grantees leveraged their funds from Council to acquire additional funding.

The date for the March 2012 meeting has not been set and a budget will need to be developed along with a project plan. Results of the March meeting will be reported during national autism month in April 2012.

XII. Report of Revenue and Expenditures

Ms. Mary Ray noted that Council will be asked to vote, at the September 12, 2011 meeting, for continuation funding (total of \$2.4M) for the second year of the research grants. The original grants and the progress reports will be sent to the grant reviewers requesting them to provide written reviews of progress.

Ms. Ray explained the funding for the NJ Autism Registry with \$150,000 of the \$500,000 annual budget awarded as small health service grants by FHS to support autism services at the County level. The Registry staff monitors the grants.

Council requested that the Autism Registry staff attend the September 12, 2011 meeting to provide additional information and respond to questions. Questions were raised concerning the cost of the Registry vs. the Cost of the Collaborative Database; the efficiency and effectiveness of autism diagnosis by the Clinical Enhancement Centers vs. cost by Child Evaluation Centers.

Four of the Clinical Enhancement Centers have requested no cost extensions, each for between six and twelve months. Not all have been approved due to issues with SAGE, the State's automated financial system. Two of the grants will be closed out effective June 30, 2011. The grantees (Children's Specialized Hospital and CNNH) will present at the September 12, 2011 Council Meeting.

XIII. Comments by public member attendees

Dr. Jill Harris, Children's Specialized Hospital, provided handouts of two posters that were presented at national autism conferences. Both projects were funded by the Council. Also, in response to comments about the autism collaborative database, Dr. Harris noted that the delay in obtaining IRB approval precluded them from entering patients prior to December 2010.

Ms. Tara Gleeson, Morrisville Hospital, questioned the difference between the Collaborative Database and NJ Autism Registry. The Collaborative Database grew out of the need for the six Clinical Enhancement Centers to collect data for research. The Centers must have IRB approval and patients/caregivers have the option to participate. The information differs from that of the Autism Registry in that the Registry is used for public health surveillance purposes. The Registry is mandated by law with healthcare providers required to enter into the Registry all patients diagnosed with autism. Parental consent is not required. The Family Health Services staff oversees both databases.

A brief history: In the early 2000's Council awarded small research grants. Then in 2008 the Council awarded six clinical enhancement grants to establish centers where clinicians could come together and over time develop standard evaluation and treatment approaches for autism. The Centers were required to collect data and submit to a Collaborative Database that, at the time, was under development. The intent was to collect data that was compatible with the national autism database (NDAR) so that the State would have a repository that was unique and positioned the State for federal funding. Difficulties by several of the Centers in obtaining approvals from the IRBs, implementation issues relating to database and policy/procedure revisions and obtaining parental consents have all resulted in less than optimal use of the Collaborative Database. Currently the Collaborative Database is fully functional and all Centers have been awarded IRB approvals and can transmit information.

Dr. Audrey Mars, Hunterdon Medical Center, noted that the Report of Revenues and Expenditures had been shared with the public in the past and asked if the public can continue to

receive the report. A copy was provided and all were informed that future reports will be available either as copies or as PowerPoint presentations.

Dr. Pnina Mintz, CNNH, commented on the Council's discussion of autism evaluation costs and noted that the costs vary among providers and it is very difficult to determine standard costs as assessments/evaluations differ among Centers.

Additional comment: Increase in the number of children diagnosed was not a requirement of the grant since significant time and resources may be invested in assessing children who ultimately are not diagnosed with ASD. Some children diagnosed with ASD are de-diagnosed by a second provider. It was noted there is a significant variation among the Clinical Enhancement Centers in their goals, activities and outcomes as each is unique with different models of care. As an example, one may be a diagnostic center with the goal of diagnosing and referring and another may be full service from screening, assessing, diagnosing and providing treatment. The Centers are evaluated on progress in accomplishing their respective goals. Trends in statistical reports can be assessed for each Center but comparing one's statistical reports to another is not a valid measurement of efficiencies or effectiveness.

Additional comments: It was noted that there is a great deal of inequality of care and that cost is a symptom of the problem. What is a standardized intervention? Diagnostic tools vary but the intent is to get clinicians together so that over time they start to develop a more standardized approach (e.g. protocols). The Council is interested in what the Centers have learned during the past three years, what are their processes and what they think are best practices and why.

With the new RFAs the Department needs to decide how to best monitor the grants. What does Council want to see the Department collect? Madeleine Goldfarb and Dr. Meyer volunteered to serve on a subcommittee to recommend to Council the information that should be captured in monitoring the grants to ensure compliance. It was noted that data from the current Centers should be available for review if they apply for the new RFAs.

Dr. Walter Zahorodny expressed concern with the frequent delays in issuing the new RFAs. There does not seem to be a sense of urgency at a time of critical need for autism research in the State.

Ms. Kirchner responded by noting that the Department is looking at all elements of the RFAs to ensure that they are aligned and that reporting requirements are clear. The RFAs are creating a new direction consistent with the intent of the Statute while serving the needs of the people of New Jersey. The Department has made significant progress since December 2010 in clarifying ethical standards for the Council and, specifically, as they relate to conflict of interest and the RFAs. As noted in her discussion of the Code of Ethics, Ms. Kirchner stated that Council members must comply with the Code of Ethics to remain in good standing as a member of the Council. Once the RFAs are published adequate time will be allocated for applicants to respond.

XIII. Adjournment

Dr. Eggerding thanked the public for their comments and called for a motion to adjourn. MOTION by Ms. Goldfarb to adjourn the meeting and seconded by Dr. Sprott.

MOTION passed with all in favor. The meeting was adjourned at 8:15PM.